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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/837,459	04/18/1997	MARIAN L. MCKEE	4995.0023	7600

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FINNEGAN HENDERSON FARABOW GARRETT &  
DUNNER  
1300 I STREET NW  
WASHINGTON, DC 200053315

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

08/837,459

Applicant(s)

MCKEE ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 1/30/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 60,66-71 and 73-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 73,74,91-95,99 and 100 is/are allowed.
- 6) ☐ Claim(s) 60,66-71,75-90,96-98,101-104 is/are rejected.
- 7) ☐ Claim(s) 60,76 and 96 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/30/2004</u> | 6) <input checked="" type="checkbox"/> Other: <u>definitions from Web</u> .             |

### **DETAILED ACTION**

Claims 1-59, 61-65, 72 have been canceled.

Claims 60, 66-71, 73-104 are pending and under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Information Disclosure Statement***

1. The information disclosure statement filed January 30, 2004 has been considered.

#### ***Rejections Withdrawn***

2. Claims 97-104 rejected under 35 U.S.C. 112, first paragraph (New Matter), has been obviated through amendment of the claims to delete the term "over expressed".
3. Claims 60, 66-96 rejected under 35 USC 112, first paragraph (New Matter) has been obviated through the responses submitted by Applicant.
4. Claim 68 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been obviated through amendment of the claim to define the specific population of milk producing animals.
5. Claims 60, 66-67, 83-84, 89, 97 rejected under 35 U.S.C. 103(a) as being unpatentable over Dougan et al (US Pat. 5,747,293) is herein withdrawn in light of the arguments and evidence submitted by Applicant showing anti-intimin antibodies do not merely treat infection but provide protection; all of the claims require the anti-intimin antibodies to provide protect against infection through blocking colonization and establishment of infection .

#### ***Allowable Subject Matter***

6. Claims 73-74, 91-95 and 99-100 define over the prior art of record and are therefore allowed.

#### ***New Grounds of Objection/Rejection***

##### ***Claim Objections***

7. Claims 60, 76 and 96 are objected to because of the following informalities: All three claims recite a semi-colon " ; " prior to the recitation of a "wherein" clause; this should be a comma " , " as the "wherein" clause does not positively set forth an additional active voice

methods steps but provides clarification of an already recited methods step. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. Claims 60, 71, 76, 78-90, 96-98, 101-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
9. All of the claims recite the phrase “to a host to generate anti-intimin antibodies”. The instant specification teaches the administration of intimin to a patient (see [0020], [0021], [0024]) to generate anti-intimin antibodies, not a host cell.
10. While the instant Specification recites the term “host”, the term is used to describe E.coli host cells (see [0058] “host bacteria is EHEC”), or host bacteria, (see paragraph [0057]) and E.coli and bacterial cells are and were not defined to be anti-intimin antibody generating hosts.
11. No E.coli host cells that generate anti-intimin antibodies evidence original descriptive support in the instant specification. No transformed E.coli host cells that generate anti-intimin antibodies have been described, suggested or taught.
12. All of the claims are directed to the administration of intimin **to a host** to generate anti-intimin antibodies. E.coli bacteria are not immunocompetent hosts, and would not generate anti-intimin antibodies, nor antibodies of any kind, absent transformation into a genetically

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engineered cell. No genetically engineered, recombinantly transformed E.coli host cells that generate anti-intimin antibodies based upon the administration of intimin to the E.coli host cell.

13. All of the claims that do not define the host to be an immunocompetent animal, are not enabled to generate anti-intimin antibodies upon administration of intimin to a host, the host being defined by the instant Specification to be an E.coli host or bacterial host cell.

14. The instantly claimed inventions also recite New Matter as no E.coli host or bacterial cells evidence original descriptive support in the instant specification that generate anti-intimin antibodies, wherein the antibodies would be generated upon administration of intimin to the host as an induction step.

15. The claims are also not enabled for the generation of antibodies through administering intimin to an E.coli host; the specification only provides enablement for the generation of antibodies by immunocompetent animals [0012] PG-Pub of instant Application US2002/0006407, such as cows, mice, rabbits, goats.

16. The originally presented claims recited the step of "administering ... intimin to a patient"; this phrase evidences original descriptive support, does not contain any new matter and is enabled. Amendment of the claims to recite a combination of claim limitations that evidence original descriptive support and is enabled could obviate this rejection (ie ----mammal-----).

17. Claim 75 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 75 recites the phrase “further comprising birthing the offspring, and preparing at least one of the offspring and at least one of the first and second food mammals as a food source for human consumption”.

No original descriptive support could be found for the phrase “birthing the offspring”. The term “offspring” is generally understood to be an animal that has already been born (see Bartleby.com: American Heritage Dictionary of the English Language definition of “Offspring”, provided herewith), and not an animal waiting to be born.

No method of process steps of “birthing” could be found in the instant Specification. While claim 74, from which claim 75 depends, finds support in the instant Specification, paragraph [0163, PG pub, page 12, US 2002/0006407], claim 75 is claiming an embodiment not described in the instant Specification. No original descriptive support could be found for the “further comprising step” set forth in claim 75. Claim 75 recites New Matter.

18. Claim 66 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 66 recites the term “wildlife” which is not defined, nor disclosed in the instant specification as an animal for the generation of anti-intimin antibodies.

Upon consideration of the definition of the term “wildlife” provided by the US Environmental Protection Agency, the meaning was found to include:

“animals and plants that grow independently of people”.

Clearly the instant specification does not evidence original descriptive support for the methods step of administering intimin to any plants, nor the claimed genus of wild animals in a method of providing passive immune protection to a patient.

While administering intimin to a wild animal could possibly and arguable be carried out, the collection and administration of the anti-intimin antibodies from the wild animal to the patient could not be carried out as the wildlife would be in the wild, and not domesticated.

The method of claim 66, that administers intimin to “wildlife”, does not evidence original descriptive support in the instant Specification and therefore recites a combination of claim limitations that sets forth New Matter.

19. Claim 79 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20. Claim 79 recites the phrase “further comprising breeding said at least one food mammal”. The instant Specification does not provide original descriptive support for the methods step of “further comprising breeding said at least one food mammal”. While the Specification teaches the importance of limiting “contaminated food (see [0004], PG-Pub), and protecting pigs, cattle, and rabbits against infection caused by EHEC pathogens through inducing and administering anti-intimin antibodies (see [0163], PG-Pub, and all examples), no additional teaching, guidance or original descriptive support could be found for breeding any of the animals that had anti-intimin antibodies administered to them.

The animals (cows, see paragraph [0163]) were administered "intimin", and the antibodies were then administered to the off-spring, but the instantly claimed invention of claim 79 comprises three steps of generating antibodies, administering antibodies and then breeding the food mammals. The instant specification is absolutely silent with respect to breeding the food mammals that have been administered anti-intimin antibodies. The combination of claim limitations recited in claim 79 constitute New Matter as original descriptive support for this methods step is not support by the instant specification.

21. Claims 66-71, 77-90, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 66-71 and 77-90 recite the terms "host" and "animal"; the term "host" being defined in the instant specification to be bacterial hosts, to include E.coli host cells. Bacteria do not generate anti-intimin antibodies, therefore the claims do not recite a combination of claim limitations that are internally consistent with the definitions provided in the instant Specification. This rejection could be obviated through amending the claims to recite the term -----mammal---- or ---patient----- instead of the term "host".

### *Conclusion*

22. This is a non-final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.



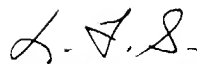
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp

June 22, 2004

  
LYNETTE A. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER GROUP